AMENDMENTS TO THE DRAWINGS

Replacement Sheets of Figs. 9A-11C are attached hereto.

The Replacement Sheets have been re-contrasted and re-copied to provide clearer, more readable pictures. The Figures have also been re-numbered with "FIG." before each Figure, and the number and capital letter for each related Figure. No new matter has been added.

REMARKS

Status of the Application

Claims 1-34 are pending in this application. The Examiner's previous allowance of all claims has currently been withdrawn in view of newly discovered prior art. The claims have been amended herein in accordance with the suggestions made in the Examiner's section 101 rejection and objections. Applicant has further amended claim 1 to recite that the acquiring of radiation absorbance images of the target element includes <u>moving a radiation source</u> through a limited plurality of angles. This feature is discussed throughout the application and is readily seen, for example, in Figure 1 and the discussion thereof.

Drawings

The Examiner objected to Figures 9A-11C due to the contrast being difficult to read, and the numbering being improper. The Replacement Sheets have been re-contrasted and re-copied to provide clearer, more readable pictures. The Figures have also been re-numbered with "FIG." before each Figure, and the number and capital letter inserted for each related Figure. No new matter has been added.

Claim Objections

The Examiner objected to claims 14-34 based on certain informalities. In particular, the Examiner states:

> In the following format (location of objection; suggestion for correction), the following correction(s) may obviate the objection(s): (claim 14, line 1, "the number"; replacing "the" with - -a- -), (claim 15, lines 7-8, "a plurality of attenuation value"; replacing "value" with - -values- -), (claim 15, lines 11-12, "the radiation absorbance projection images"; deleting "the"), (claim 25. line 2, "a different angles"; deleting "a"), and (claim 25, lines 5-6, "a plurality of attenuation value"; replacing "value" with - -values- -).
>
> Claims 16-24 and 26-34 are objected to by virtue of their dependency. For purposes of examination, the claims have been treated as such. Appropriate correction is required.

The Applicant has made the changes as suggested by the Examiner.

Claim Rejections Under 35 U.S.C. §101

The Examiner has rejected claims 25-34 under 35 U.S.C. 101 because the claimed invention is directed to non-statutory matter. Specifically, the Examiner states:

> Claims 25-34 claim(s) a computer program. Computer programs are not physical "things." They are neither computer components nor statutory processes, as they are not "acts" being performed. Such claimed computer programs do not define any structural and functional interrelationships between the computer program and other claimed elements of a computer, which permit the computer program's functionality to be realized. In contrast, a claimed computer-readable medium encoded with a computer program is a computer element which defines structural and functional interrelationships between the computer program and the rest of the computer which permit the computer program's functionality to be realized, and is thus statutory.

Applicant notes that the claim already recited "the computer program code being embodied in a computer readable medium," however, Applicant has amended claim 25 herein in an attempt to adapt it more closely to the Examiner's suggestion.

Claim Rejections Under 35 USC §102 Over Tam

The Examiner has rejected claims 1, 2, 5, 14, 15, 18, 25, and 28 under 35 U.S.C. 102(b) as being anticipated by U.S. 5,270,926 (Tam.). Specifically, the Examiner states:

Claims 1, 15, and 25

> Tam discloses a method, system, and computer readable medium encoded with a computer program for imaging, comprising acquiring radiation absorbance images of a target element through a limited plurality of angles with a source and detector (fig. 12, and abstract, lines 1-3), and applying an iterative reconstruction algorithm (fig. 9, and col. 5, lines 26-28) to generate a three-dimensional reconstruction of the target element (abstract, lines 1-3), wherein the iterative reconstruction algorithm is applied using cone-beam forward projection (fig. 9, #72) and back projection (fig. 9, #64).

Claim 2

Tam further discloses wherein the radiation absorbance images are acquired by transmitting x-ray energy from an x-ray source (fig. 12, #22) through the target element (fig. 12, #20) to an x-ray detector (fig. 12, #24).

Claims 5, 18, and 28

Tam further discloses wherein radiation absorbance images are acquired through a range of angles that is between about 30 and 120 degrees (fig. 12, #30).

Claim 14

Tam would necessarily have a number of iterations less than or equal to about 10, when convergence is found almost immediately (fig. 9, #70).

The present invention is directed to Tomosynthesis. Each claim in the patent application refers to Tomosythesis. For example, claim 1 recites a "tomosythesis method for creating a three-dimensional reconstruction of a target element." Claim 15 recites a "system for three-dimensional tomosythesis imaging of a target element." Tam relates exclusively to a Computed Tomography or CT system. The title of the Tam patent is "method and apparatus for reconstructing a three dimensional Computerized Tomography (CT) image of an object . . ." In Figure 1, Tam illustrates a classic computerized tomography system in which the source 22 and detector 24 rotate together in a complete circle around the object of interest. [Tam, column 2, lines 50 to 61.] Tam's goal is to improve this conventional CT scanning by applying computations to make up for missing data during image reconstruction.

Tomosynthesis is fundamentally a different approach to imaging than Computed Tomogography. This is described in the application at page 2 of the application as follows:

The most widely used three-dimensional x-ray imaging technique is computed tomography ("CT"). A CT scanner contains a rotating frame that has one or more x-ray tubes mounted on one side and one or more detectors on the opposite side. As the rotating frame spins both the x-ray tube and the detector around the patient, numerous projections of the x-ray beam attenuated by a cross section slice of the body are acquired. These projections are then used to reconstruct cross-sectional images of the body. Despite the fact that CT has been found useful in detecting lesions in the breast, it is not suitable as a technique

> for regular breast imaging due to the high dose required to take a number of projections (approximately 100 to 1,000 projections) and the low spatial resolution (on the order of a millimeter). In addition, the CT projections mix attenuation effects from other organs of the body (such as those within the chest cavity) with the attenuation of the breast, which can distort information about the breast and causes these interposed organs to be irradiated. Still further, the cost of CT scanning is too high to permit its use as part of an annual exam.
>
> A three-dimensional imaging approach called "tomosynthesis" has also been developed. Tomosynthesis is a technique that allows the reconstruction of tomographic planes on the basis of the information contained in a series of projections acquired from a series of viewpoints about the target object. They need not be regularly spaced, numerous, or arranged in any regular geometry. The tomosythesis technique is promising in that it may provide improved spatial differentiation of nearby tissues at very high resolution comparable to projection 2D imaging, with limited radiation. The problem of 3D reconstruction from tomosynthesis projections has been described as intractable by those skilled in the art.

An introduction to the geometries and calculations used in Tomosynthesis (and which are distinctly different from those portrayed in the conventional CT system of Tam) can be found in Niklason et al. Digital Tomosynthesis in Breast Imaging, Radiology 1997: 205:300-406, which is of record in this application. Prior art Tomosynthesis systems performed these calculations as follows (as quoted from the application on pages 8-9):

> Tomosynthesis can take advantage of the high efficiency of a digital detector in acquiring low dose breast images. Prior to the present invention, appropriate reconstruction methods that make good use of the low dose projections and the acquisition geometry of the tomosynthesis system 10 have not been deployed. For an initial evaluation, Niklason implemented a "shift-and-add" method that is similar to backprojection [Niklason et al, 1997]. Methods used by others [Chakraborty et al, 1984; Haaker et al, 1985; Suryanarayanan et al, 2000] essentially did not handle the limited statistics in low dose projection images. In theory, they were not suitable in the case of limited number of projections and limited angular range. Therefore, the three-dimensional information extracted by these methods was limited, which resulted in poor quality reconstructions.

It was against this backdrop that the inventor created a novel combination of processing steps to solve the problems in the art. Tam does not disclose all of the features of claims 1 and 15 at least because Tam does not disclose Tomosynthesis imaging.

Tam's lack of a teaching of Tomosythesis imaging also appears through Tam's lack disclosure of a number of the specific geometric and other elements recited in the dependent claims. For example, in dependent claims 5, 18, and 28, applicant recites that the acquisition of radiation absorbance images of the target element through a limited plurality of angles are further obtained through a range of angles that is between about 30 and 120 degrees. This feature can best be illustrated by reference to Figure 1 of the application which shows that the source 12 moves through 11 discrete positions to obtain images at angles as recited. This limited sweep through a small number of discrete positions and at limited angles stands in sharp contrast to the CT system of Tam, wherein the source is rotated 360 degrees around the object. [See circular scanning trajectory 30 in Figures 1 and 12.]

With regard to claim 14, the Examiner states that "Tam would necessarily have a number of iterations less than or equal to about 10, when convergence is found almost immediately (fig. 9, #70)." But element 70 in Figure 9 is nothing more than a test that is repeated throughout repetitions of the iterative loop until a convergence test is met [column 8, lines 45 to 56], there is never any suggestion that convergence will be immediate or almost immediate. In fact, Cheng notes of Tam that "Projection data are corrected by a priori information on the object support, upper and lower bounds of projection values, and reprojected to calculate the missing data. These steps are repeated until some convergence criterion is satisfied. ***However, the convergence and optimality of this iterative algorithm have not been established.***" [Cheng, column 2, lines 7 to 17.]

Claim Rejections Under 35 USC §102 Over Cheng

The Examiner has rejected claims 1, 2, 6, 11, 15, 19, 24, 25, 29, and 34 under 35 U.S.C. 102(b) as being anticipated by U.S. 5,909,476 (Cheng). Specifically, the Examiner states:

Claims 1, 15, and 25

> Cheng et al. discloses a method, system, and computer readable medium encoded with a computer program for imaging, comprising acquiring radiation absorbance images of a target element through a limited plurality of angles with a source and detector (fig. 5), and applying an iterative reconstruction algorithm (title) to generate a three-dimensional reconstruction (col. 3, line 35) of the target element (abstract, lines 1-3), wherein the iterative reconstruction algorithm (col. 6, line 27) is applied using cone-beam forward projection (fig. 4, #406) and back projection (fig. 4, #407).
>
> *Claim 2*
>
> Cheng et al. further discloses wherein the radiation absorbance images are acquired by transmitting x-ray energy from an x-ray source (col. 3, lines 25-26) through the target element (fig. 1, #103) to an x-ray detector (fig. 1, #106).
>
> *Claims 6, 11, 19, 24, 29, and 34*
>
> Cheng et al. further discloses wherein the iterative reconstruction algorithm is necessarily a maximum likelihood algorithm implemented using an expectation-maximization algorithm (col. 8, lines 20-37).

Cheng likewise does not relate to Tomosynthesis. Rather, it relates to cone-beam tomography – in particular, Cheng's device is a microscope. As a result, the x-ray source 101 in Cheng does not move through a limited plurality of angles. Rather, the x-ray source of Cheng remains still during imaging, and the e-beam is electro-magnetically steered to sweep through a cone. This is very different from the geometry and operation of the presently claimed invention as discussed above and illustrated in Figure 1.

<u>Claim Rejections Under 35 USC §103</u>

The Examiner has rejected claims 3, 7, 16, 20, 26, and 30 under 35 U.S.C. 103(a) as being unpatentable over Tam as applied to claims 2, 15, and 25, and further in view of U.S. 6,483,890 (Malamud). Specifically, the Examiner states:

> *Claims 3, 16, and 26*

Tam discloses a method, system, and medium as recited above.

However, Tam fails to disclose wherein an x-ray detector is a digital x-ray detector having a plurality of detector pixels.

Malamud teaches wherein an x-ray detector is a digital x-ray detector (col. 1, lines 15-24) having a plurality of detector pixels (fig. 2, #16).

It would have been obvious, to one having ordinary skill in the art at the time the invention was made, to incorporate the method, system, and medium of Tam with the detector of Malamud, since one would be motivated to make such a modification for more easily processing signals with a computer (col. 1, lines 15-24) as implied from Malamud.

Claims 7, 20 and 30

Tam further discloses wherein the three-dimensional reconstruction of the target element would necessarily be represented as an array of voxels having a uniform or non-uniform size in three-dimensions, which are characteristic of 3D CT images (abstract, line 2).

Applicant submits that these claims are not obvious at least because of the fundamental differences between Tam and the presently claimed invention as described above with respect to the anticipation rejections. Each of those differences also renders these claims non-obvious over Tam, or combinations involving Tam. In addition, with respect to claims 7, 20 and 30, Applicant notes that Tam does not state that Tam uses voxel based reconstruction, but rather Tam states that Tam reconstructs 3D images slice by slice by creating 2-dimensional projection images in the plane of the slice. [See, e.g., column 10, lines 32-43.] Tam thus expressly teaches something very different from the recitations of claims 7, 20 and 30 – with no teaching or suggestion that the recitations of claims 7, 20 and 30 should be attempted. This provides an independent basis for the non-obviousness of these claims over Tam.

The Examiner has rejected claims 3, 7-10, 16, 20-23, 26, and 30-33 under 35 U.S.C. 103(a) as being unpatentable over Cheng et al. as applied to claims 2, 15, and 25, and further in view of Malamud. Specifically, the Examiner states:

Claims 3, 16, and 26

Cheng et al. discloses a method, system, and medium as recited above.

However, Cheng et al. fails to disclose wherein an x-ray detector is a digital x-ray detector having a plurality of detector pixels.

Malamud teaches wherein an x-ray detector is a digital x-ray detector (col. 1, lines 15-24) having a plurality of detector pixels (fig. 2, #16).

It would have been obvious, to one having ordinary skill in the art at the time the invention was made, to incorporate the method, system, and medium of Cheng et al. with the detector of Malamud, since one would be motivated to make such a modification for more easily processing signals with a computer (col. 1, lines 15-24) as implied from Malamud.

Claims 7, 20, and 30

Cheng et al. further discloses wherein the three-dimensional reconstruction of the target element is represented as an array of voxels having a uniform or non-uniform size in three-dimensions (fig. 2).

Claims 8, 21, and 31

Cheng et al. further discloses wherein a forward projection step is implemented by ray tracing from the x-ray source to a detector pixel and the forward projection of the target element is obtained by necessarily repeating the ray tracing for each detector pixel to calculate an attenuation value for each voxel in order to reproject the volume (col. 7, lines 7-10).

Claims 9, 10, 22, 23, 32, and 33

Cheng et al. further discloses wherein a back projection step is implemented by necessarily locating detector pixels containing attenuation information relating to a selected voxel and using those pixels to update the attenuation value of the selected voxel, and wherein the back projection step includes performing a back projection for at least each voxel corresponding to a three-dimensional reconstruction of the target element (col. 7, lines 11-21).

Applicant submits that these claims are not obvious at least because of the fundamental differences between Cheng and the presently claimed invention as described above with respect to the anticipation rejections. Namely, Cheng relates to cone beam tomography, and in particular, microtomography, rather than Tomosynthesis as recited in the claims. As a result, Cheng's x-ray source 101 does not move through a limited plurality of angles. Rather, the x-ray

source of Cheng remains still during imaging, and the e-beam is electro-magnetically steered to sweep through a cone. This is very different from the geometry and operation of the presently claimed invention as discussed above and illustrated in Figure 1. Each of those differences also renders these claims non-obvious over Tam, or combinations involving Tam.

The Examiner has rejected claims 4, 17, and 27 under 35 U.S.C. 103(a) as being unpatentable over Tam as applied to claims 1, 15, and 25. Specifically, the Examiner states:

> Tam discloses a method, system, and medium as recited above. Tam further discloses wherein radiation absorbance images are acquired through a number of angles less than a number (col. 2, lines 56-64).
>
> However, Tarn fails to disclose a number of angles less than or equal to about 100.
>
> It would have been obvious, to one having ordinary skill in the art at the time the invention was made, to incorporate the method, system, and medium of Tam with the above number of angles, since where the general conditions of a claim are disclosed in the prior art, discovering the working ranges involves only routine skill in the art. One would be motivated to make such a modification to speed up imaging (col. 1, lines 45-46) as implied from Tam.

It would not, as the Examiner suggests, been obvious to reduce the number of angles or number of images needed by Tam as such a reduction (typically from 100 to 1000 or more typically around 300) would necessarily reduce resolution. The system of Tam was not, and was not suggested to be, effective at fewer than about 100 images. Applicant's system and method, in sharp contrast, can offer high resolution with many fewer images. This does not result from simply reducing the number of images, but from changing the nature of the image acquisition from CT to Tomosythesis, and then developing new methods and system for reconstructing 3D images using Tomosythesis. This is not disclosed, taught or suggested by Tam.

CONCLUSION

If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event the U.S. Patent and Trademark Office determines that an extension is required, applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to Deposit Account No. 141449 referencing docket no. 102282-0015.

Dated: September 15, 2006

Respectfully submitted,

By ______________________

Ronald E. Cahill
Registration No.: 38,403
NUTTER MCCLENNEN & FISH LLP
World Trade Center West
155 Seaport Boulevard
Boston, Massachusetts 02210-2604
(617) 439-2782
(617) 310-9782 (Fax)
Attorney for Applicant

1523425.1